

heart pulse rate that deviates from a normal resting rate whereby the heart rate range is compromised."

As pointed out in the specification, and as supported in the published articles annexed hereto, a compromised heart pulse rate (referred to in the literature as a "Reduced Heart Rate Variability" is indicative of an abnormal condition without regard to its cause or nature, and constitutes a "Mortality Risk."

The purpose of the exercise program set forth in claim 1 is to cause the patient's heart rate range to approach a range that is normal for that patient, and in doing so to overcome his abnormal condition whatever its nature and cause.

To this end, in the course of the program as the patient exercises, his heart pulse rate is continuously monitored, for the indicated pulse rate guides the program.

The patient is subjected "to a series of exercise-relaxation cycles in which in the course of each cycle the patient experiences a surge of energy causing his pulse rate to reach a peak value that depends on the patient's physical state, at which point the patient relaxes and his heart rate, because of a pendulum effect, induced in the patient's heart, swings down from a peak value to a rest rate value to produce a spiked heart wave."

The pendulum effect is the key to the effectiveness of the program, for applicant has found that the human heart behaves in a manner similar to that of an oscillating

pendulum in which the amplitude of oscillation depends on the force of the impulse which incites the pendulum into motion.

As shown in Fig. 2, the successive exercise-relaxation cycles produce a spiked heart wave that expands the heart beat range that runs from the rate at rest to the maximum rate resulting from stress.

The program is continued "until the patient's maximum pulse rate and resting pulse rate approach those of an individual having a normal heart rate range and free from the abnormal condition."

Rejections under Sections 101 and 112:

These rejections are interrelated. The Examiner contends that the specification "does not clearly describe how the method functions to treat a patient having an abnormal condition, regardless of its nature and origin." And the Examiner also contends that the invention lacks "utility" on the grounds that there is no evidence or convincing scientific explanation of how the method operates to produce the claimed utility.

The fact that a "compromised heart rate range" reflects an abnormal condition in a patient regardless of its nature and origin is fully supported in the scientific literature.

Enclosed herewith is an article entitled "Reduced Heart Rate Variability and Mortality Risk in an Elderly Cohort - Framingham Heart Study" by Tsuji et al. This article appeared in Circulation (Vol. 20, No. 2, Aug. 1994) published by the American Heart Association.

Also enclosed is an article by Moser et al. "Heart Rate Variability as a Prognostic Tool in Cardiology" published in the same issue of Circulation. This article deals with the "Prognostic value of heart rate variability with respect to survival."

Clearly, HRV or heart rate range of a patient is a key to mortality, and a patient having a reduced HRV or a compromised range is at risk. But the concern of the present invention is not HRV measurement for prognosis, but an exercise program for a patient with a reduced HRV that will increase his HRV and thereby improve his condition.

It is submitted that the method claimed is fully disclosed in the specification and that the Section 112 rejection is therefore unwarranted. And it is further submitted that there is scientific and clinical evidence to substantiate the utility of the claimed method, and that the Section 101 rejection is therefore unwarranted.

#### Section 103 Rejections:

Claim 1 to 6 are rejected as being unpatentable over Shimizu et al., and claim 7 is rejected on Simizu et al. in view of Takara, both under Section 103. It is submitted that these rejections are untenable.

Shimizu discloses a jogging watch that incorporates a pulse detector which counts the number of heart beats produced by exercise to sense an increase in physical strength as a result of jogging or other exercise activity. Takara shows a stress level measuring device based on pulse rate.

The present invention also makes use of a device to continuously monitor the heart pulse rate in the course of exercise. But the method set forth in the claims subjects a patient whose heart rate is being monitored to a series